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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,194	10/28/2003	Denis Francois Hochstrasser	A36054-PCT-USA-A 072874.0	4418

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/695,194	HOCHSTRASSER ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 January 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *19April2006*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached Detailed Action.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Final Office Action, received 30 January 2006, is acknowledged. Claims 1-47 are pending. Claims 20, 23-28 and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

2. Claims 1-19, 21-22, and 29-46 solely drawn to method and kit for diagnosis of TSE using polypeptide are under consideration.

Rejections Withdrawn

3. The rejection of claims 1-19, 21, 22, and 29-46 under 35 U.S.C. 112, second paragraph, indefiniteness for all other components in samples, is withdrawn in light of applicants' argument.

Rejections Maintained

4. The rejection of claim 1-10, 16, 19, 21, 22, 37, and 39 under 35 U.S.C. 112, first paragraph, scope of enablement for utilizing any/all other body fluids or utilizing any other component having a molecular weight in the range of 1000-100000, is maintained for reasons of record.

Applicants argue that the specification discloses a comparative study demonstrating that peaks of about 1010 to 31800 Da can be used to diagnose BSE in plasma samples (paragraphs 124-127), and a method of determining these markers using SELDI (examples 6 and 7). Thus, markers of BSE in plasma samples are identified by molecular weight.

The examiner notes that the application as submitted does not contain any paragraphs numbered 124-127.

The examiner has considered applicants' argument, but does not find it persuasive for the reasons put forth in the prior explanations. Examples 6 and 7 do appear to indicate that

plasma from BSE infected subjects have discrete peak differences with plasma from normal subjects. However, the claims are drawn to markers within a range of from 1010-31,800, not to the discrete peaks evidenced in the examples. Thus, a marker with a molecular weight of about 16,000 is being claimed. None of the examples provided in the specification are drawn to this particular molecular weight. In addition, the only named proteins are cystatin C and isoforms of hemoglobin.

Applicants argue that it is commonly known in the art that many proteins found in the blood will also be found in urine.

The examiner has considered applicants' argument, but does not find it persuasive. As put forth in the prior explanations, the specification teaches only two fluids, CSF and plasma, but no evidence that the differential presence exists in any other bodily fluid. Even applicants' argument that "many proteins found in the blood will also be found in urine" indicates that the presence of a protein in the blood does not correlate directly with the proteins being found in another bodily fluid, i.e., urine, because not all proteins found in blood will be also found in urine.

5. The rejection of claims 1-19, 21, 22, and 29-46 under 35 U.S.C. 112, second paragraph, indefiniteness for "determining whether the test amount is consistent with a diagnosis of TSE", is maintained for reasons of record.

Applicants argue that the claims do not require that a diagnosis of TSE has been determined prior to the determination of the presence/absence of a polypeptide. Instead, the invention recites determining a test amount of a polypeptide in a sample, comparing the test amount to a reference amount of polypeptide, and determining whether the test amount is consistent with a diagnosis of TSE.

The examiner has considered applicants' argument, but does not find it persuasive. If the claimed invention is a method of diagnosis of a TSE by comparing a test amount of a marker in the body fluid of a subject with a reference amount of said marker found in a normal sample of the same body fluid from a normal subject, wherein a particular difference (increase or decrease) of the marker indicates TSE, then that wording should be indicated. However, in the instant claims, the only endpoint is if the test amount is consistent with a diagnosis of TSE, which indicates that TSE has already been diagnosed in the subject in question.

Conclusion

6. Claims 1-19, 21, 22, and 29-46 remain rejected.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

May 16, 2006